

PATENT COOPERATION TREATY

REC'D 04 SEP 2006
WIPO PCT

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
GREGORY A. NELSON
AKERMAN SENTERFITT
P.O. BOX 3188
WEST PALM BEACH, FL 33402-3188

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **31 AUG 2006**

Applicant's or agent's file reference

7230-21 WO

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US05/01581

International filing date (day/month/year)

21 January 2005 (21.01.2005)

Priority date (day/month/year)

22 January 2004 (22.01.2004)

International Patent Classification (IPC) or both national classification and IPC

IPC: A61K 31/35(2006.01)

USPC: 514/460

Applicant

UNIVERSITY OF MIAMI

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201

Date of completion of this opinion

06 August 2006 (06.08.2006)

Authorized officer

Jean C. Witz

Telephone No. (571) 272-0700

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US05/01581

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US05/01581

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>2-5, 11-14, 33-37</u>	YES
	Claims <u>1, 6-10, 15-32</u>	NO
Inventive step (IS)	Claims <u>2-5, 33-37</u>	YES
	Claims <u>1, 6-32</u>	NO
Industrial applicability (IA)	Claims <u>1-37</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1, 6-10, and 15-32 lack novelty under PCT Article 33(2) as being anticipated by U.S. Patent 6,582,723 to Gorsek.

The claims are drawn to compositions and methods of treating tumor cells with CoEnzyme Q10. The patent to Gorsek teaches the treatment of cancer and the prevention of metastases by the administration of CoEnzyme Q10. Non-disclosed claimed limitations are deemed inherent in the disclosure of the amounts effective to treat cancer.

Claims 11-14 lack an inventive step under PCT Article 33(3) as being obvious over U.S. Patent 6,582,723 to Gorsek.

The claims require the topical administration of the CoEnzyme Q10 as well as the concurrent administration of conventional antineoplastic compounds. Cancers are conventionally treated wherever they appear such that the formulation for the appropriate administration of a conventional anticancer composition is deemed well with the skill of the practitioner. Further, cancer treatment is conventionally performed in combination or cocktails of multiple agents; therefore, administration of known chemotherapeutic agents with another known chemotherapeutic agent, CoEnzyme Q10, is further deemed well within the skill of the practitioner.

Claims 2-5 and 33-37 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the formulation of CoEnzyme Q10 with the other claimed ingredients.

Claims 1-37 meet the criteria set out in PCT Article 33(4), and thus meet industrial applicability because the subject matter claimed can be made or used in industry.